



Document Title

**Summary of the residues in or on treated products, food and feed
Fluopicolide + Fluoxastrobin QS 350 (200+150 g/L)**

Data Requirement(s)

Regulation (EC) No 1107/2009 & Regulation (EU) No 284/2013

Document MCP

Section 8: Residues in or on treated products, food and feed

**According to the Guidance Document SANCO/10181/2013 for applicants
on preparing dossiers for the approval of a chemical active substance**

Date

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Version history

Date [yyyy-mm-dd]	Data points containing amendments or additions ¹ and brief description	Document identifier and version number
2020-04-08	Original Document MCP – Section 8	M-682109-01
2020-04-29	Addition of information on fluopicolide	M-682109-021

¹ It is suggested that applicants adopt a similar approach to showing revisions and version history as outlined in SANCO/10180/2013 Chapter 4, 'How to revise an Assessment Report'.

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CP 8 RESIDUES IN OR ON TREATED PRODUCTS, FOOD OR FEED

Fluopicolide was included in Annex I to Council Directive 91/414/EEC in 2010 (Commission Directive 2010/15/EU, Entry into Force on June 1, 2010). The expiration of approval of fluopicolide is May 31, 2023 (Commission Implementing Regulation (EU) 2017/1527). The Supplementary Dossier contains only data which were not submitted at the time of the Annex I inclusion of fluopicolide under Council Directive 91/414/EEC and which were therefore not evaluated during the first EU review. All data which were already submitted by Bayer AG (former Bayer CropScience) for the Annex I inclusion under Council Directive 91/414/EEC are contained in the Draft Assessment Report (DAR) and its Addenda, and are included in the Baseline Dossier provided by Bayer AG.

The formulation Fluopicolide + Fluoxastrobin FS 350 (200+150 g/L), abbreviation FLC + FXA FS 350, is a flowable concentrate for seed treatment formulation (FS) containing 200 g/L of fluopicolide. This formulation is registered in Europe under the trade name Sceptic Gold FLC + FXA FS 350. It was not a representative formulation of Bayer AG for the Annex I inclusion of fluopicolide under Council Directive 91/414/EEC.

Fluopicolide (AE C638206) is a fungicidal active substance developed by Bayer. It is the only active substance in Europe representing a class of chemistry (pyridinylmethyl-benzamides) with a unique mode of action via delocalization of a spectrin-like protein in the Oomycetes fungi.

Fluopicolide is active against a wide range of Oomycete fungi, low dose rates against a wide range of Oomycete (Phycomycetes) diseases including downy mildews (*Pseudoperonospora*, *Peronospora*, *Bremia*), late blight (*Phytophthora*). It is also effective against downy mildews and some *Pythium* species causing damping off at emergence time.

Fluopicolide is redistributed via the xylem and effective disease control can be achieved from foliar and seed applications. Fluopicolide is used in mixture in a range of foliar formulations in potatoes, horticultural crops and industrial crops such as oilseed.

Fluopicolide has a long track record of safe use in a large number of targeted crops within industrial crops.

Fluopicolide can be formulated with other active ingredients in different types of formulations to optimise and complete its activity.

The development of resistances of Oomycetes against existing, well-established fungicide groups represent a threat for European farmers by increasing the complexity of their plant protection programs leading to severe economic impacts. With Fluopicolide, farmers in EU-27 have access to a modern tool for their integrated crop protection programs, contributing to effective and sustainable management of resistance development and preserving high level of protection against Oomycete diseases.

By reducing the Oomycete damages, applications of Fluopicolide + Fluoxastrobin FS 350 on target crops contribute to the achievement of optimum emergence insuring yield and quality, thus securing sufficient supply of high-quality oilseed for European consumer destinations and markets abroad, for the processing industry.

All relevant metabolism and residue data in support of this use are summarized in Document MCA, Section 6